

SEP 1 9 2000

Appendix D – 510(k) Summary**Baby Dopplex® 4002 – BD4002**

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Name of Device: Baby Dopplex® 4002 – Twins (BD4002)

Manufactured by: Huntleigh Diagnostics Ltd
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Cardiff
South Glamorgan CF24 5HN
Wales, U.K.

Contact Person at Manufacturing Facility:

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Date summary prepared: 30 May 2000

Classification Name

Fetal Ultrasonic Monitor and Accessories (21 CFR § 884.2660)

Predicate Devices

Baby Dopplex 4000 (BD4000) K990569.

Device Description

The BD4002 is a fetal monitor capable of monitoring either singleton or twin fetuses. The device produces cardiotocographs (CTG) and gives indication of uterine activity by processing received ultrasound/electrical signals. In basic format, the device performs antepartum fetal monitoring and uterine activity functions. By connecting separate modules to the BD4002 main unit, intrapartum monitoring operations are enabled.

The antepartum fetal monitor uses ultrasound transducer(s) to monitor fetal heart rate(s), and a force sensor (toco) located on the outside of the maternal abdomen to monitor uterine activity.

The intrapartum fetal monitor produces fetal cardiotocographs (CTG), via ultrasound signal(s) and/or fetal ECG signal (via a scalp clip). It can also monitor uterine activity through a force sensor activated during contractions, either internally (via an IUP catheter), or externally using the standard contractions transducer (toco).

The ultrasound transducer(s) use burst tone Doppler ultrasound at 1.5MHz.

The BD4002 has been tested to ensure compliance with internationally recognised medical electrical equipment standards. Tests have been performed in accordance with the requirements of IEC601-1, BS EN60601-1, BS EN 60601-1-2, BS EN55011 & DIN VDE 0750-1. A checklist of Essential Requirements tests has been compiled in accordance with the direction of the Medical Devices Directive 93/42/EEC. Biocompatibility has been assessed in line with the principles contained within BS EN30993-1.

The medical practitioner uses the device as one of the indicators, when monitoring fetal wellbeing. The device configuration can be summarised as follows: -

Intended use

The BD4002 device performs the same functions as the BD4000. It can also monitor twin fetuses simultaneously. With the BD4000 two separate units had to be connected together to allow that monitoring function to be performed.

The fetal parameters are displayed in the same way as those of the predicate devices.

The following table briefly compares the monitoring characteristics of the applicant device to its predicate devices.

Monitoring Mode	Baby Dopplex® 4002	Baby Dopplex® 4000
Monitoring fetal heart rate using ultrasound	Yes	Yes
Detect fetal movement	Yes	Yes
Monitoring twin fetal heart rate using ultrasound	Yes	Yes ⁽¹⁾ 2 off BD4000 Units required
Monitor fetal heart rate using FECG	Yes ⁽¹⁾	Yes ⁽¹⁾ 2 off BD4000 Units required

NB: ⁽¹⁾ optional feature which requires additional module(s).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2000

Ms. Audrey A. Witko
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Re: K001882
Baby Dopplex® 4002 – Twins (BD4002)
Dated: June 8, 2000
Received: June 21, 2000
Regulatory Class: II
21 CFR 884.2740/Procode: 85 HGM

Dear Ms. Witko:

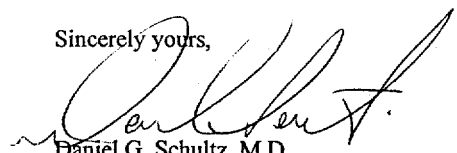
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Appendix F – Indications For Use Summary

510(k) Number (if known): K 001 882

Device Name: Baby Dopplex® 4002 – Twins (BD4002)

Indications for Use

The BD4002 is a fetal monitor capable of monitoring either singleton or twin fetuses. The device produces cardiocotographs (CTG) and gives indication of uterine activity by processing received ultrasound/electrical signals.

In basic format, the device performs antepartum fetal monitoring and uterine activity functions. By connecting separate modules to the BD4002 main unit, Intrapartum monitoring operations are enabled.

Fetal movement detection is also monitored by processing the received Doppler signals.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over the counter use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K 001 882